

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: C. Randall Mills et al. )  
Serial No.: 10/828,653 )  
Filed: April 20, 2004 )  
For: PROCESS AND APPARATUS )  
FOR TREATING IMPLANTS )  
COMPRISING SOFT TISSUE )  
Group Art Unit: 1744 )  
Examiner: Regina M. Yoo )  
Confirmation No.: 4918 )

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

We, C. Randal Mills, John R. Bianchi, Michael R. Roberts, and Chandrasekaran Nataraj, declare the following:

1. We are each listed as joint inventors of subject matter disclosed and claimed in US Patent Application No. 10/828,653 ("the '653 patent application").
2. The '653 application was filed on April 4, 2004. It is our belief that the claims pending in the '653 application are set forth in the response dated October 14,

2008, and those claims relate to a process for making an implant more suitable for implantation into a recipient ("the Claimed Process").

3. This Declaration is being provided to establish a date of conception and reduction to practice of the Claimed Process in the United States on a date prior to June 6, 2002, which is the purported effective filing date of United States Patent Application No. 10/164,725 ("Ogle"), which was cited in a final Office Action mailed to the Applicant on December 30, 2008 in the subject application.

4. On a date prior to June 6, 2002 the Claimed Process was conceived by one or more of the joint inventors.

5. On a date prior to June 6, 2002 the Claimed Process was successfully reduced to practice in the United States under the direction of one or more of the joint inventors. Specifically, under the direction of John Bianchi, laboratory technicians took bone-tendon-bone grafts and put them on tensioners. Tension was applied to the tendon, and the tensioned implants were subjected to a process for making the implant more suitable for implantation into a recipient. In that process, the implant comprising soft tissue was contacted with a series of solutions, including an oxidizing sterilant (hydrogen peroxide). The process was performed on these implants prior to June 6, 2002.

6. To evidence conception and reduction to practice of the Claimed Process, attached hereto as Exhibits A-C are photographs showing the bone-tendon-bone grafts treated according to the Claimed Process. Specifically, the photographs show bone-tendon-bone grafts that were put on tensioners. Tension was applied to the tendon, and the tensioned implants were subjected to a process for making an implant more

suitable for implantation into a recipient. In that process, the implant comprising soft tissue was contacted with a series of solutions, including a protective agent (alcohol), an oxidizing sterilant (hydrogen peroxide) and a rinsing fluid. Exhibit A shows implants prior to processing. Exhibit B shows implants after processing, but before removal from the tensioners. Exhibit C shows implants after processing and after removal from the tensioners. From left to right in Exhibits A-C, the first, third and fifth implants were subjected to tension and the second, fourth and sixth were not.

7. The photographs do not have a date on their face indicating when they were created. However, they were originally created as electronic files. Electronic files have metadata associated with them. This metadata includes the date that the files were created. On information and belief, we declare that the metadata associated with these photographs indicates that they were created before June 6, 2002.

8. We certify that all statements made herein of our own knowledge are true, and that all statements made herein on information and belief are believed to be true. We understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.

  
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C. Randal Mills

June 26, 2009  
Date

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John R. Bianchi

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Date

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Michael R. Roberts

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Date

\_\_\_\_\_  
Chandrasekaran Nataraj

\_\_\_\_\_  
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O. Randal Mills

  
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John R. Bianchi

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Date

29-June-2009  
Date

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Michael R. Roberts

\_\_\_\_\_  
Date

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Chandrasekaran Nataraj

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C. Randal Mills

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Date

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John R. Bianchi

\_\_\_\_\_  
Date



Michael R. Roberts

25 JUN 2009

Date

Chandrasekaran Nataraj

Date

Declaration re: 10/828,653  
MRL 25 JUN 2009  
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1915/15672US01

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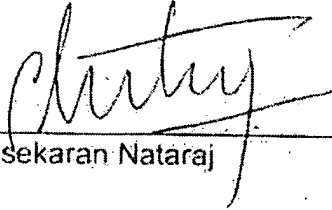
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C. Randal Mills

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Date

\_\_\_\_\_  
John R. Bianchi

\_\_\_\_\_  
Date

Michael R. Roberts



Chandrasekaran Nataraj

Date

6/29/09

Date



Exhibit A

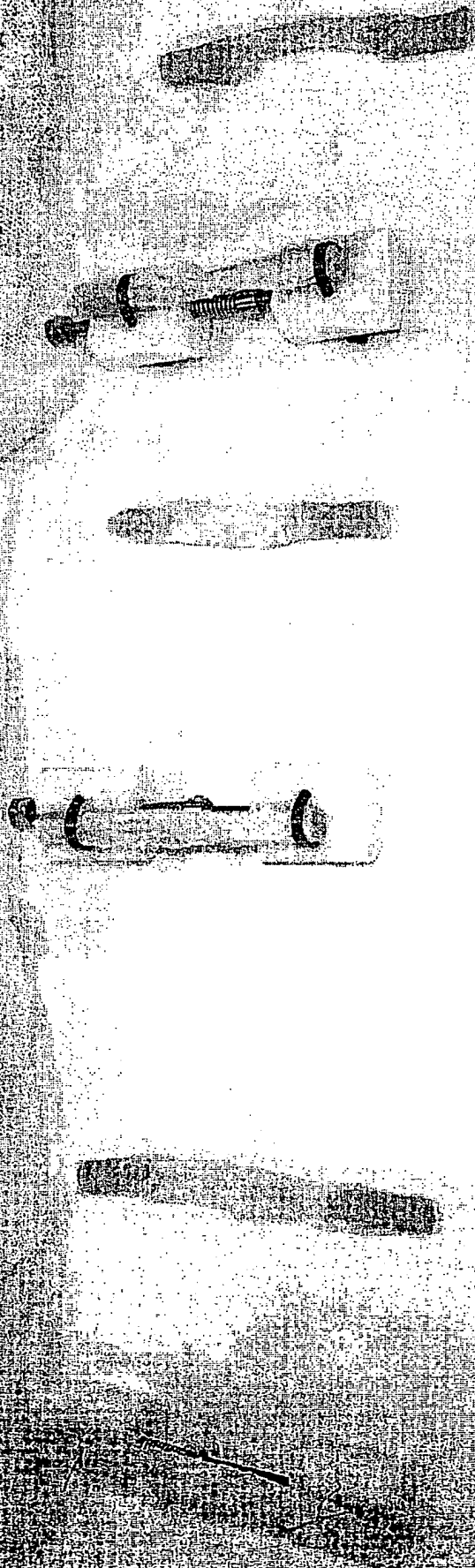


Exhibit B

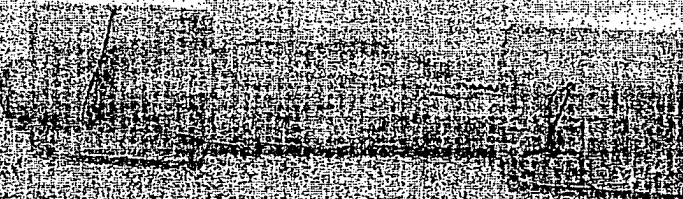
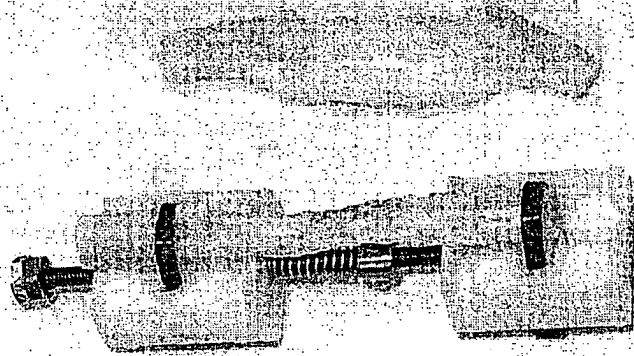


Exhibit C

